ISO/TC 84/WG 3 ad hoc 5
Needle-free injectors for medical use

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PATH Testing - Review of Tests

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PATH Jet Injection Tests

Force test and Penetration test

For each test:

- Test objectives
- Description
- Advantages
- Disadvantages
- Areas of concern

Force Test - Objective

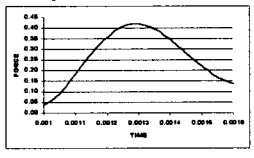
To compare different devices

To predict which will be clinically successful?

Force Test - Description

Shoot at a force sensor.

Graph force curve for each shot (time vs.. force).



Force test - Advantages

Can measure changes during the course of a single injection.

Can see if one injector has higher/lower pressures than another.

Force Test - Disadvantages

There is no direct connection between the results of this test and clinical results.

Must specify:

- Force sensor specifications
- Data acquisition specifications
- Calibration details

Force Test - Areas of Concern

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Test validation

Force Test - Conclusion

At this time, the force test cannot reliably predict which device(s) will be clinically successful.

Penetration Test- Objective

To compare different devices

To predict which will be clinically successful?

Penetration Test- Description

Shoot through consistent medium with consistent backing. (PATH developed an arm model for Norplant® implant training.)

Observe result: liquid on the surface and hole in the "skin material" material

Optional: weigh fluid on the surface

Penetration Test-Advantages

Tests performance directly (tests all aspects of device: stream quality, interface with "skin", etc.)

Clear result – goes in or doesn't.

May identify other potential problems (i.e., lacerations)

Penetration Test- Disadvantages

Material has different properties than skin; no direct connection between and clinical results.

Can only compare devices that have some bad and some good injections.

Some potential problems will not be seen in this test (welting, bleeding, pain).

Penetration Test - Areas of Concern

Consistent material properties – "skin" and backing material.

Consistent technique.

If weight of fluid on the surface is measured, care must be taken to collect all fluid.

Penetration Test-Conclusion

At this time, the penetration test cannot reliably predict which device(s) will be clinically successful.

Example of test results

Rating	Clinical Results	*In vitro* measurement
Highest	Device A	Device A
		Device D
	Device B	
	Device C	
		Device C
Lowest	Device D	Device B

Value of these tests

Developmental tool

- evolving - may lead to tests that are more reliable and clinically predictive
- can be useful when comparing similar devices or different versions of a given device
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